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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,341	10/25/2001	Bradley Stuart Galer	1203-01	3845

7590 11/27/2002

IP Department  
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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/045,341	GALER, BRADLEY STUART
	Examiner Simon J. Oh	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3,6 and 8-12 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1, 3, 6, and 8-12 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,5</u> .	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's Amendment A, received on 3 September 2002. Receipt is acknowledged of the applicant's Supplemental Information Disclosure Statement, received on 1 October 2002.

### ***Response to Arguments***

Applicant's arguments with respect to Claims 1, 3, 6, and 8-12 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "said neuropathic pain" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 6, 8, 9, 11, and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hind (U.S. Patent No. 5,411,738).

The Hind patent teaches methods and compositions for reducing pain from shingles by topical administration of lidocaine at a dosage below that which achieves analgesia without inducing anesthesia or systemic side effects (See Column 3, Lines 1-17 and 29-36). In the disclosed compositions, lidocaine is present in amounts of about 1 to 25% by weight (See Column 3, Lines 55-65). Included in the disclosure are details of a study in which patches containing 5% lidocaine as well as other excipients are administered to patients (See Column 15, Lines 11-18).

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 6, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hind.

The relevant details of the Hind patent are given in the above rejection under 35 U.S.C. 102.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Botknecht *et al.*

The relevant details of the Hind patent are given in the above rejection under 35 U.S.C. 102. Hind does not indicate that the disclosed compositions and methods can be used to treat pain from the group consisting of myofascial pains, fibromyalgia, bursitis, costrochondritis, repetitive motion injuries, carpal tunnel syndrome, and nociceptive pain.

The Botknecht *et al.* patent teaches a method of relieving pain by using a topical composition comprising a local anesthetic (See Column 1, Lines 5-10; and Column 3, Line 54 to Column 4, Line 26). The method of pain relief is directed to joint disorders, such as tennis elbow, bursitis, and the various types of arthritis (See Column 1, Lines 29-48). The local anesthetic component of the composition is preferably lidocaine, including its pharmaceutically acceptable salts; the local anesthetic may be present in an amount ranging from 0.1% to 10% by weight (See Column 5, Line 46-54; and Claims 1, 8, 14 and 17).

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hind and Botknecht *et al.* into the objects of Claim 10. The teachings of Hind provide for topical compositions comprising lidocaine and methods to treat pain in a way that produces analgesia without causing anesthesia. The teachings of Botknecht *et al.* provide for topical compositions comprising lidocaine for the purpose of treating pain from joint disorders. It is the position of the examiner that one of ordinary skill in the art, at the time the claimed invention was made, would be motivated to use the compositions and methods of treatment of Hind to treat the joint disorders described in Botknecht *et al.*, in place of the compositions of Botknecht *et al.*, with a reasonable expectation of success.

Thus, the claimed invention as a whole is *prima facie* obvious.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjo  
November 21, 2002

*THURMAN K. PAGE*  
SUPERVISOR PATENT EXAMINER  
~~TECHNOLOGY CENTER 1600~~